

## **EXHIBIT A**



Re Application of:

David O'Leary

RECEIVED

Due Date: 6/30/03

Mailed: 6/2/03

Mailer: Jin Zhang

For: Reservoir Pressure System for Medicament Inhaler

Serial No. 09/888,199

TECHNOLOGY CENTER 8400

Docket: IVAL-127-1

56327-149

In the above matter, the following has been received in the U.S. Patent and Trademark Office on the date stamped hereon.

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|--------------------------------------------------------------------------------------|--------------------------------------------------------|
| <input type="checkbox"/> Specification, Abstract and<br>( ) Claims — ( ) Total Pages | <input type="checkbox"/> Extension of time             |
| <input type="checkbox"/> Declaration and Power                                       | <input type="checkbox"/> Amendment                     |
| <input type="checkbox"/> Drawing ( ) sheets                                          | <input checked="" type="checkbox"/> Cert. of Mailing   |
| <input type="checkbox"/> Assignment                                                  | <input type="checkbox"/> Maintenance Fee Transmittal   |
| <input type="checkbox"/> Check \$                                                    | <input type="checkbox"/> Affidavit (w/w/o Exhibits)    |
| <input type="checkbox"/> Request for Recordation                                     | <input type="checkbox"/> Notice of Appeal              |
| <input type="checkbox"/> Information Disclosure Statement                            | <input type="checkbox"/> Brief ( ) copies              |
| <input type="checkbox"/> Small entity verification                                   | <input type="checkbox"/> Issue fee transmittal         |
| <input checked="" type="checkbox"/> Amendment and Response; Petition to Revoke       | <input checked="" type="checkbox"/> Transmittal letter |
| <input type="checkbox"/>                                                             |                                                        |



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: David O'Leary, et al. Examiner: Nihir Patel  
Serial No.: 09/888,199 Group Art Unit: 3743  
Filing Date: June 23, 2001  
Docket Number: 56327-149 (IVAL-127-1)  
Title: RESERVOIR PRESSURE SYSTEM FOR MEDICAMENT INHALER

CERTIFICATE OF MAILING (37 C.F.R. 1.8(a))

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.

Date: \_\_\_\_\_

Mail Stop Petition  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Sir:

Enclosed herewith for filing in connection with the above-identified patent application are the following:

- 1) Amendment and Response;
- 2) Petition to Revive; and
- 3) Acknowledgment Postcard.

No further fees are believed due; however please charge any fees which may be due, or credit any overpayment, to Deposit Account Number 50-1133.

Respectfully submitted,

Date: 2 JUNE 2003

Mark G. Lapping, P.C.  
Registration No.: 26,618  
McDERMOTT, WILL & EMERY  
28 State Street  
Boston, Massachusetts 02109  
Telephone: (617) 535-4043  
Facsimile: (617) 535-3800



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: David O'Leary, et al.  
Serial No.: 09/888,199  
Filing Date: June 23, 2001  
Docket Number: 56327-149 (IVAL-127-1)  
Title: RESERVOIR PRESSURE SYSTEM FOR MEDICAMENT INHALER

Examiner: Nihir Patel  
Group Art Unit: 3743

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**CERTIFICATE OF MAILING (37 C.F.R. 1.8(a))**

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.

Date: \_\_\_\_\_

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Mail Stop Petition  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**PETITION FOR REVIVAL UNDER 37 CFR §1.137(b)**

Sir:

Applicants respectfully request revival of the subject application in accordance with 37 CFR §1.137(b).

Apparently, an Office Action in the subject application was mailed to the assignee of the Applicants on August 13, 2002. However, the assignee of the Applicants has no record of receiving the Office Action.

On May 20, 2003, the undersigned counsel for the Applicants first received a copy of the Office Action from the above identified examiner during an interview with the examiner at the USPTO in a related application.

The six-month statutory period for response to the Office Action expired February 13, 2003. The delay in filing a timely response to the Office Action was unintentional. A full and complete Response to the Office Action is filed herewith. A Notice of Abandonment has not been received by the Applicants. Applicants respectfully request revival of the subject Application in accordance with 37 CFR §1.137(b).

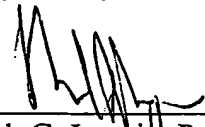
Since the failure to file a timely and proper response to the Office Action dated August

13, 2002 appears to be due to the assignee of the Applicants' failure to receive the Office Action from the USPTO, it is believed no fees are due with respect to the submission of this paper. However, the Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 50-113.

Respectfully submitted,

Date: \_\_\_\_\_

2 JUNE 2003



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THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: David O'Leary, et al.  
Serial No.: 09/888,199  
Filed: June 23, 2001  
Title: Reservoir Pressure System For Medicament Inhaler  
Group Art Unit: 3743  
Examiner: Nihir Patel  
Atty. Docket No.: NHC0031A-USA (56327-149, IVAL-127-1)

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**CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8**

I hereby certify that this correspondence is deposited with the United States Post Office as First Class Mail on the date indicated below in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

\_\_\_\_\_  
Date: \_\_\_\_\_

Mail Stop Non-Fee Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**AMENDMENT AND RESPONSE**

In response to the Office Action dated August 13, 2002, please consider the following remarks and enter the amendments herein. No new matter is presented by the amendments herein.

## AMENDMENT

### *In the Claims*

Please amend claim 1 as set forth below:

1. (currently amended) An inhaler comprising:
  - a sealed reservoir including a dispensing port;
  - a channel communicating with the dispensing port and including a pressure relief port;
  - a conduit providing fluid communication between an interior of the sealed reservoir and the pressure relief port of the channel;
  - a cup assembly movably received in the channel and including,
    - a recess adapted to receive medicament when aligned with the dispensing port,
    - a first sealing surface adapted to seal the dispensing port when the recess is unaligned with the dispensing port, and
    - a second sealing surface adapted to ~~sealing~~ seal the pressure relief port when the recess is aligned with the dispensing port and unseal the pressure relief port when the recess is unaligned with the dispensing port.

**In the Abstract**

Please amend the abstract as set forth below:

~~A new and improved~~ An inhaler includes an accurate and consistent mechanical dose metering system that dispenses dry powdered medicament in discrete amounts or doses for patient inhalation, a pressure relief system that manages pressure within a medicament reservoir of the inhaler to ensure consistently dispensed doses, and a dose counting system indicating the number of doses remaining in the inhaler.



## REMARKS

Claims 1 through 17 remain in the application. Claim 1 has been amended to correct a clerical error.

In the Office Action, the abstract was rejected because the abstract as originally filed compared the invention with the prior art. By this amendment, the abstract has been amended to obviate this rejection.

No new matter has been added. As set forth below, all claims 1-17 are believed to be in condition for allowance.

### A. Claim Rejections under 35 U.S.C. §112.

In the Office Action, claims 1-17 were rejected under 35 U.S.C. §112 second paragraph, as being indefinite. These rejections are respectfully traversed.

Claims 1-17 were rejected under 35 U.S.C. §112 second paragraph, as being indefinite. More particularly, referring to claim 1, the Examiner stated that there was insufficient antecedent basis for limitations “the dispensing port”, “the sealed reservoir”, “the pressure relief port”, “the channel”, and “the recess”.

Applicants respectfully point out that in claim 1, the subject application defines:

1. An inhaler comprising:

a sealed reservoir including a dispensing port;

a channel communicating with the dispensing port and including a pressure relief port;

a conduit providing fluid communication between an interior of the sealed reservoir and the pressure relief port of the channel;

a cup assembly movably received in the channel and including,

a recess adapted to receive medicament when aligned with the dispensing port,

a first sealing surface adapted to seal the dispensing port when the recess is unaligned with the dispensing port, and

a second sealing surface adapted to sealing the pressure relief port when

the recess is aligned with the dispensing port and unseal the pressure relief port when the recess is unaligned with the dispensing port.

Applicants respectfully submit that antecedent basis (as underlined) are provided for limitations “the dispensing port”, “the sealed reservoir”, “the pressure relief port”, “the channel”, and “the recess” in claim 1.

For the same reason, it is submitted that there is sufficient antecedent basis for the limitations of claims 2-17. In view of the above remarks, there is no proper basis for the rejections under 35 U.S.C. §112, and those rejections should be reconsidered and withdrawn.

**B. Claims 1, 2, 4-7, 9 and 16 (Rejection Under 35 U.S.C. §102(b))**

Claims 1, 2, 4-7, 9 and 16 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,065,471 to Schaeffer et al. Issue is taken with that position.

Claim 1 is an independent claim. Claims 2, 4-7, 9 and 16 are dependent claims, which directly or indirectly depend from claim 1, providing further limitations to claim 1.

The invention of the subject application, as claimed in claim 1, defines an inhaler having a channel communicating with a dispensing port and including a pressure relief port, and a cup assembly movably received in the channel. In contrast, Schaeffer does not disclose an inhaler having a channel and a cup assembly. Therefore, claim 1, as well as claims 2-17 depend therefrom should be considered patentable over Schaeffer. The rejection should be reconsidered and withdrawn.

**C. Claims 3, 9-15 and 17 (Rejection Under 35 U.S.C. §103(a))**

Claim 3 was rejected under 35 U.S.C. 103(a) as being unpatentable over Schaeffer et al. in view of U.S. Patent No. 6,029,661 to Whaley et al.

Claims 9 and 10 were rejected under 35 U.S.C. 103(a) as being unpatentable over Schaeffer et al. in view of U.S. Patent No. 5,119,806 to Palson et al.

Claims 11, 12, 14, and 15 were rejected under 35 U.S.C. 103(a) as being

unpatentable over Schaeffer et al. in view of U.S. Patent No. 6,405,727 to MacMichael et al.

Claim 13 was rejected under 35 U.S.C. 103(a) as being unpatentable over Whaley et al. in view of Palson et al.

Claim 17 was rejected under U.S.C. 103(a) as being unpatentable over Schaeffer et al. in view U.S. Patent No. 5,740,792 to Ashley.

Claims 3, 9-15 and 17 are all dependent claims, which directly or indirectly depend from Claim 1. Claims 3, 9-15 and 17 include the limitation of Claim 1, providing further limitations to claim 1.

As discussed above, Schaeffer does not disclose or suggest a device having a channel and a cup assembly as defined in claim 1 of the subject application. The other references do not teach or suggest a channel and cup assembly as defined in claim 1 as well. Therefore, claim 1, as well as claims 2-17 depend therefrom, of the subject application, should be considered patentable over Schaeffer alone or in combination with the other references. Those rejections should be reconsidered and withdrawn.

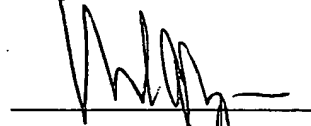
## CONCLUSION

On the basis of the foregoing amendments and remarks, Applicants respectfully submit that all of pending claims 1-17 are in condition of allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

The Commissioner is hereby authorized to charge any additional fees that may be due, or credit any overpayment to Deposit Account No. 50-1133.

Date: 12 JUNE 2003

Respectfully submitted,



Mark G. Lappin, P.C.  
Registration Number 26, 618  
McDERMOTT, WILL & EMERY  
28 State Street  
Boston, Massachusetts 02109  
Tel: (617) 535-4043  
Fax: (617) 535-3800

## **EXHIBIT B**

## Interview Summary

Application No.

09/888,199

Applicant(s)

O'LEARY, DAVID

Examiner

Nihir Patel

Art Unit

3743

All participants (applicant, applicant's representative, PTO personnel):

(1) Nihir Patel. (3) \_\_\_\_\_

(2) Mark Lappin. (4) \_\_\_\_\_

Date of Interview: 06-03-03

Type: a) ☐ Telephonic b) ☐ Video Conference  
c) ☒ Personal [copy given to: 1) ☐ applicant 2) ☒ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.  
If Yes, brief description: \_\_\_\_\_

Claim(s) discussed: 1.

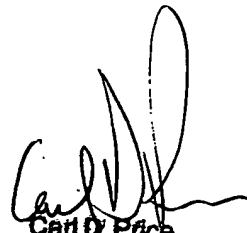
Identification of prior art discussed: Schaeffer.

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: The applicant's invention discloses a cup assembly movably received in the channel where as Schaeffer (reference) does not. The application will be considered for allowance upon a further search by the examiner.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

  
Carl D. Price  
Primary Examiner

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

  
Examiner's signature, if required

## **EXHIBIT C**

<b>Interview Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/888,199		O'LEARY, DAVID	
	<b>Examiner</b>		<b>Art Unit</b>	
	Nihir Patel		3743	

All participants (applicant, applicant's representative, PTO personnel):

- (1) Nihir Patel. (3) Henry Bennett.  
 (2) Mark Lappin. (4) \_\_\_\_.

Date of Interview: October 2<sup>nd</sup>, 2003.

Type: a) ☐ Telephonic b) ☐ Video Conference  
 c) ☒ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.  
 If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: 1.

Identification of prior art discussed: Schaeffer.

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: If claim 1 is amended to include a linear channel the application will be considered allowable upon a further search to be conducted by the examiner.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required



## **EXHIBIT D**

Re Application of: **David O'Leary, et al.**

Due Date:

Mailed: **12/12/03**

Mailer: **Keiko Nakagawa**

For: **Reservoir Pressure System for Medicament Inhaler**

Serial No. **09/888,199**

Patent No.

NHC0031A  
Docket: **(IVAL-127-1)**

In the above matter, the following has been received in the U.S. Patent and Trademark Office on the date stamped hereon.

☐ Specification, Abstract and

( ) Claims — ( ) Total Pages

☐ Declaration and Power

☐ Drawing ( sheets)

☐ Assignment

☐ Check \$

☐ Request for Recordation

☐ Information Disclosure Statement

☐ Small entity verification

☐

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☐ Extension of time

☒ Amendment **Supplemental, 7 pages**

☐ Cert. of Mailing

☐ Maintenance Fee Transmittal

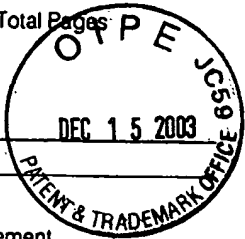
☐ Affidavit (w/wo Exhibits)

☐ Notice of Appeal

☐ Brief ( ) copies

☐ Issue fee transmittal

☐ Transmittal letter



56327-149

DEC 1 2003  
PATENT & TRADEMARK OFFICE

DRS

PCM

**THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: David O'Leary, et al.  
Serial No.: 09/888,199  
Filed: June 23, 2001  
Title: Reservoir Pressure System For Medicament Inhaler  
Group Art Unit: 3743  
Examiner: Nihir Patel  
Atty. Docket No.: NHC0031A-USA (56327-149, IVAL-127-1)

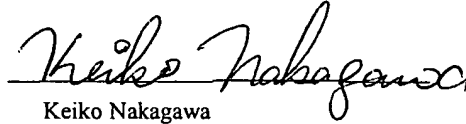
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**MAILING UNDER 37 C.F.R. 1.8(a)**

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December 12, 2003

Date:

  
Keiko Nakagawa

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Mail Stop Non-Fee Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**SUPPLEMENTAL AMENDMENT**

This paper supplements the Amendment and Response filed June 3, 2003.

Please amend the claims as follows:

1. (Currently Amended)

Please change "a channel" to read --a linear channel--.

**Remarks**

Claims 1 thorough 17 remain in the application. Claim 1 has been amended to more clearly define the invention, in view of the discussion between the undersigned and Examiner Bennett and Patel on October 2, 2003. Claim 1 now defines the channel as "linear", as shown in the figures. No new matter is added.

The Response and Amendment filed June 3, 2003, at page 5 argued against the outstanding rejection based on U.S. Patent No. 6,065,471 to Schaeffer et al. ("Schaeffer"). In order more clearly distinguish the subject matter of claim 1, and that of claims 2-17 dependent thereon, claim 1 has now been amended to define the channel as linear.

As discussed, and agreed to, at the October 2, 2003 interview, Schaeffer does not disclose or suggest a device having a linear channel and a cup assembly as defined in claim 1 of the subject application. The other references do not teach or suggest a channel and cup assembly as defined in claim 1 as well. Therefore, claim 1, as well as claims 2-17 dependent therefrom, of the subject application, should be considered patentable over Schaeffer alone or in combination with the other references. Those rejections should be reconsidered and withdrawn.

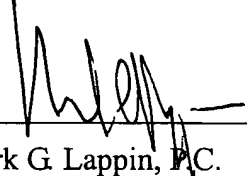
### CONCLUSION

On the basis of the foregoing amendments and remarks, Applicants respectfully submit that all of pending claims 1-17 are in condition of allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

The Commissioner is hereby authorized to charge any additional fees that may be due, or credit any overpayment to Deposit Account No. 50-1133.

Respectfully submitted,

Date: 12/12/03



Mark G. Lappin, P.C.  
Registration Number 26, 618  
McDERMOTT, WILL & EMERY  
28 State Street  
Boston, Massachusetts 02109  
Tel: (617) 535-4043  
Fax: (617) 535-3800

**Listing of Claims**

1. (Currently amended): An inhaler comprising:
  - a sealed reservoir including a dispensing port;
  - a linear channel communicating with the dispensing port and including a pressure relief port;
  - a conduit providing fluid communication between an interior of the sealed reservoir and the pressure relief port of the channel;
  - a cup assembly movably received in the channel and including,
    - a recess adapted to receive medicament when aligned with the dispensing port,
    - a first sealing surface adapted to seal the dispensing port when the recess is unaligned with the dispensing port, and
    - a second sealing surface adapted to seal the pressure relief port when the recess is aligned with the dispensing port and unseal the pressure relief port when the recess is unaligned with the dispensing port.
2. (Original) An inhaler according to claim 1, wherein the cup assembly includes a sealing spring biasing the first sealing surface against the reservoir.
3. (Original) An inhaler according to claim 1, wherein the reservoir includes a collapsible bellows adapted to increase pressure within the interior of the reservoir upon being collapsed, when the pressure relief port is sealed.
4. (Original) An inhaler according to claim 1, wherein the cup assembly includes a cup received in a cup sled movable within the channel, the cup defining the recess and the first sealing surface, and the sled defining the second sealing surface.
5. (Original) An inhaler according to claim 4, wherein the sled defines an indentation adapted to align with and unseal the pressure relief port when the first sealing surface is

aligned with the dispenser port.

6. (Original) An inhaler according to claim 4, wherein the cup assembly includes a sealing spring between the cup and the cup sled, biasing the first sealing surface of the cup against the reservoir.

7. (Original) An inhaler according to claim 1, wherein the channel extends linearly and the cup assembly is movable in opposing directions within the channel.

8. (Original) An inhaler according to claim 1, further comprising:

a cup spring biasing the cup assembly along the channel; and  
a yoke movable between at least two positions and including a ratchet engaging the cup assembly and preventing movement of the cup assembly when the yoke is in one of the positions and allowing movement of the cup when the yoke is in another of the positions.

9. (Original) An inhaler according to claim 8, wherein the cup spring biases the cup assembly to a position wherein the recess is unaligned with the dispensing port of the reservoir.

10. (Original) An inhaler according to claim 9, wherein the yoke further includes a push bar adapted to align the recess of the cup assembly with the dispensing port upon movement of the yoke to one of the positions.

11. (Original) An inhaler according to claim 9, further comprising:

at least one movable cam including at least two successive cam surfaces; and  
a spring biasing the yoke against the cam such that movement of the cam causes the yoke to successively engage the cam surfaces and move the yoke between the at least two positions of the yoke.

12. (Original) An inhaler according to claim 11, wherein the cam includes three successive cam surfaces for moving the yoke between three positions, wherein the ratchet is adapted to hold the recess unaligned with the dispensing port when the yoke is in a first and a second of the three positions, and allow movement of the cup assembly when the yoke is in a third of the three positions.

13. (Original) An inhaler according to claim 12, further comprising a collapsible bellows adapted to increase pressure within the interior of the reservoir upon being collapsed, and wherein the yoke is arranged to collapse the bellows when the yoke is in the first and the second positions.

14. (Original) An inhaler according to claim 11, further comprising:

a mouthpiece for patient inhalation; and

a cover movable to open and close the mouthpiece, wherein the at least one cam is secured to the cover for movement therewith, whereby opening and closing the mouthpiece causes the yoke to move between the three positions of the yoke.

15. (Original) An inhaler according to claim 14, wherein the cam is movable by rotation.

16. (Original) An inhaler according to claim 1, wherein the reservoir includes a volume of dry powdered medicament.

17. (Original) An inhaler according to claim 1, further comprising:

a pawl movable along a predetermined path upon movement of the recess of the cup assembly from the dispensing port; and

a dose counter including,

a bobbin,

a rotatable spool,



a rolled ribbon received on the bobbin and rotatable about an axis of the bobbin, the ribbon having indicia thereon successively extending between a first end of the ribbon secured to the spool and a second end of the ribbon positioned on the bobbin, and

teeth extending radially outwardly from the spool into the predetermined path of the pawl so that the spool is rotated by the pawl and the ribbon is advanced onto the spool during the metering of a dose.

Re Application of: **David O'Leary, et al.**

Due Date:

Mailed: **12/12/03**

Mailer: **Keiko Nakagawa**

For: **Reservoir Pressure System for Medicament Inhaler**

Serial No. **09/888,199**

Patent No.

Docket: **NHC0031A  
(IVAL-127-1)**

In the above matter, the following has been received in the U.S. Patent and Trademark Office on the date stamped hereon.

- |                                                                                      |                                                                            |
|--------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| <input type="checkbox"/> Specification, Abstract and<br>( ) Claims — ( ) Total Pages | <input type="checkbox"/> Extension of time _____                           |
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| <input type="checkbox"/> Check \$ _____                                              | <input type="checkbox"/> Affidavit (w/wo Exhibits)                         |
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| <input type="checkbox"/> Small entity verification                                   | <input type="checkbox"/> Issue fee transmittal                             |
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## **EXHIBIT E**



**THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Inventor application of: David O'Leary, et al.  
Serial No.: 09/888,199  
Filed: June 23, 2001  
Title: Reservoir Pressure System For Medicament Inhaler  
Group Art Unit: 3743  
Examiner: Nihir Patel  
Atty. Docket No.: IVAL-127-1

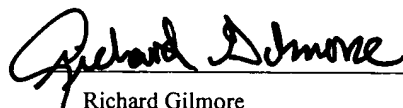
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**MAILING UNDER 37 C.F.R. 1.8(a)**

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January 17, 2006

Date:



Richard Gilmore

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Mail Stop: Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**REVISED SUPPLEMENTAL AMENDMENT**

This Revised Supplemental Amendment replaces the earlier filed Supplemental Amendment dated December 12, 2003. The Revised Supplemental Amendment starts below.

As a supplement to the amendment filed in response to the Office Action of June 3, 2003, please amend this application as follows.

Claim amendments are provided in the listing of claims which start on page 2 of this paper. Remarks begin on page 6 of this paper.

## **Amendments to the Claims**

This listing of claims will replace all prior versions and listings of claims in the subject application.

### **Listing of Claims**

1. (Currently amended): An inhaler comprising:
  - a sealed reservoir including a dispensing port;
  - a linear channel communicating with the dispensing port and including a pressure relief port;
  - a conduit providing fluid communication between an interior of the sealed reservoir and the pressure relief port of the channel;
  - a cup assembly movably received in the channel and including,
    - a recess adapted to receive medicament when aligned with the dispensing port,
    - a first sealing surface adapted to seal the dispensing port when the recess is unaligned with the dispensing port, and
    - a second sealing surface adapted to seal the pressure relief port when the recess is aligned with the dispensing port and unseal the pressure relief port when the recess is unaligned with the dispensing port.
2. (Original) An inhaler according to claim 1, wherein the cup assembly includes a sealing spring biasing the first sealing surface against the reservoir.
3. (Original) An inhaler according to claim 1, wherein the reservoir includes a collapsible bellows adapted to increase pressure within the interior of the reservoir upon being collapsed, when the pressure relief port is sealed.
4. (Original) An inhaler according to claim 1, wherein the cup assembly includes a cup received in a cup sled movable within the channel, the cup defining the recess and the first sealing surface, and the sled defining the second sealing surface.

5. (Original) An inhaler according to claim 4, wherein the sled defines an indentation adapted to align with and unseal the pressure relief port when the first sealing surface is aligned with the dispenser port.
6. (Original) An inhaler according to claim 4, wherein the cup assembly includes a sealing spring between the cup and the cup sled, biasing the first sealing surface of the cup against the reservoir.
7. (Original) An inhaler according to claim 1, wherein the channel extends linearly and the cup assembly is movable in opposing directions within the channel.
8. (Original) An inhaler according to claim 1, further comprising:
  - a cup spring biasing the cup assembly along the channel; and
  - a yoke movable between at least two positions and including a ratchet engaging the cup assembly and preventing movement of the cup assembly when the yoke is in one of the positions and allowing movement of the cup when the yoke is in another of the positions.
9. (Original) An inhaler according to claim 8, wherein the cup spring biases the cup assembly to a position wherein the recess is unaligned with the dispensing port of the reservoir.
10. (Original) An inhaler according to claim 9, wherein the yoke further includes a push bar adapted to align the recess of the cup assembly with the dispensing port upon movement of the yoke to one of the positions.
11. (Original) An inhaler according to claim 9, further comprising:
  - at least one movable cam including at least two successive cam surfaces; and

a spring biasing the yoke against the cam such that movement of the cam causes the yoke to successively engage the cam surfaces and move the yoke between the at least two positions of the yoke.

12. (Original) An inhaler according to claim 11, wherein the cam includes three successive cam surfaces for moving the yoke between three positions, wherein the ratchet is adapted to hold the recess unaligned with the dispensing port when the yoke is in a first and a second of the three positions, and allow movement of the cup assembly when the yoke is in a third of the three positions.

13. (Original) An inhaler according to claim 12, further comprising a collapsible bellows adapted to increase pressure within the interior of the reservoir upon being collapsed, and wherein the yoke is arranged to collapse the bellows when the yoke is in the first and the second positions.

14. (Original) An inhaler according to claim 11, further comprising:

a mouthpiece for patient inhalation; and

a cover movable to open and close the mouthpiece, wherein the at least one cam is secured to the cover for movement therewith, whereby opening and closing the mouthpiece causes the yoke to move between the three positions of the yoke.

15. (Original) An inhaler according to claim 14, wherein the cam is movable by rotation.

16. (Original) An inhaler according to claim 1, wherein the reservoir includes a volume of dry powdered medicament.

17. (Original) An inhaler according to claim 1, further comprising:

a pawl movable along a predetermined path upon movement of the recess of the cup assembly from the dispensing port; and

a dose counter including,

a bobbin,

a rotatable spool,

a rolled ribbon received on the bobbin and rotatable about an axis of the bobbin, the ribbon having indicia thereon successively extending between a first end of the ribbon secured to the spool and a second end of the ribbon positioned on the bobbin, and

teeth extending radially outwardly from the spool into the predetermined path of the pawl so that the spool is rotated by the pawl and the ribbon is advanced onto the spool during the metering of a dose.



### **Remarks**

Claims 1 through 17 remain in the application. Claim 1 has been amended to more clearly define the invention, in view of the discussion between the undersigned and Examiner Bennett and Patel on October 2, 2003. Claim 1 now defines the channel as "linear", as shown in the figures. No new matter is added.

The Response and Amendment filed June 3, 2003, at page 5 argued against the outstanding rejection based on U.S. Patent No. 6,065,471 to Schaeffer et al. ("Schaeffer"). In order more clearly distinguish the subject matter of claim 1, and that of claims 2-17 dependent thereon, claim 1 has now been amended to define the channel as linear.

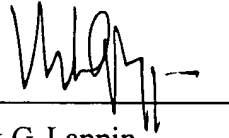
As discussed, and agreed to, at the October 2, 2003 interview, Schaeffer does not disclose or suggest a device having a linear channel and a cup assembly as defined in claim 1 of the subject application. The other references do not teach or suggest a channel and cup assembly as defined in claim 1 as well. Therefore, claim 1, as well as claims 2-17 dependent therefrom, of the subject application, should be considered patentable over Schaeffer alone or in combination with the other references. Those rejections should be reconsidered and withdrawn.

## CONCLUSION

On the basis of the foregoing amendments and remarks, Applicants respectfully submit that all of pending claims 1-17 are in condition of allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

The Commissioner is hereby authorized to charge any additional fees that may be due, or credit any overpayment to Deposit Account No. 50-2638.

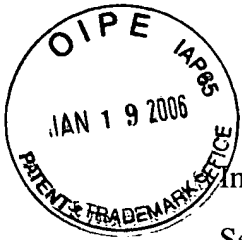
Respectfully submitted,



Date: January 17, 2006

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## **EXHIBIT F**



THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: David O'Leary, et al.  
Serial No.: 09/888,199  
Filed: June 23, 2001  
Title: Reservoir Pressure System For Medicament Inhaler  
Group Art Unit: 3743  
Examiner: Nihir Patel  
Atty. Docket No.: IVAL-127-1

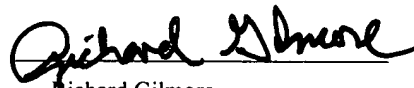
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a cup spring biasing the cup assembly along the channel; and  
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a dose counter including,

a bobbin,

a rotatable spool,

a rolled ribbon received on the bobbin and rotatable about an axis of the bobbin, the ribbon having indicia thereon successively extending between a first end of the ribbon secured to the spool and a second end of the ribbon positioned on the bobbin, and

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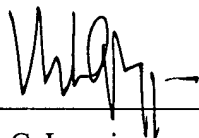
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The Commissioner is hereby authorized to charge any additional fees that may be due, or credit any overpayment to Deposit Account No. 50-2638.

Respectfully submitted,



Date: January 17, 2006

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